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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,068	04/20/2004	Marco Cavaleri	PC 19450C	6785

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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05/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/829,068

Applicant(s)

CAVALERI ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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Claims 65-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how a composition which is lyophilized can have a measurable pH.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 65-71 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Malabarba et al (U.S. Patent No. 5,750,509).

Malabarba et al disclose a composition comprising dalbavancin and a stabilizer (column 28, lines 9-12) and also disclose said composition in the form of a powder (column 28, line 13). Malabarba et al further disclose the combination of dalbavancin in combination with a sugar, such as lactose (column 27, lines 54-56). The claimed compositions are anticipated by Malabarba et al. In addition, if there are any differences between the claimed composition and the prior art composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's disclosure, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Applicant's arguments filed May 1, 2007 have been fully considered but they are not persuasive.

Applicant contends that Malabarba et al does not disclose MAG, the pH recited in claim 68 or Bo mole percent recited in claim 70.

Applicant further contends that a lyophilized dalbavancin composition that is not stabilized or pH adjusted had an initial Bo MAG content of 4.5% and an initial Bo content of 83.6% as shown at Table 7 and Figs. 1-2 (composition D) in U.S. Patent No. 7,119,061. These arguments have not been found persuasive. Composition D, as shown in Table 4 of U.S. Patent No. 7,119,061, contains dalbavancin in that is not

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stabilized or pH adjusted. Note that said composition, which is not pH adjusted and pH of 3.01. The pH of 3.01 is within the range of the claimed pH of "about 3 to about 5" (claim 65). Further note that pH of "about 3.5" (claim 68) also reads on pH of 3.01 since the present specification fails to present definition of the term "about". Also, the composition disclosed by Malabarba et al comprises the addition of stabilizer (column 28) and disclose dalbavancin in combination with lactose (column 27). Therefore, the composition D of U.S. Patent No. 7,119,061 is not the same as the prior art composition. With respect to the amounts of MAG and Bo present in the prior art composition, applicant has not presented any evidence showing how the amount of MAG and Bo of the prior art composition differs from the claimed composition. Note that a composition disclosed by Malabarba et al containing lactose and having pH of 3.01 would be expected to have MAG and Bo levels the same or closely related to the MAG and Bo levels of the claimed compositions.

Claims 65-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawai et al (U.S. Patent No. 6,774,104) in combination with Malabarba et al (U.S. Patent No. 5,750,509).

Sawai et al disclose stabilized lyophilized composition comprising a cyclic polypeptide and an effective stabilizer, wherein the composition has pH of 4.5-7.0 (column 9, lines 51-61). Sawai et al also disclose disaccharides as a stabilizers (column 9, lines 9-15). But Sawai et al do not disclose the use of a cyclic polypeptide such as dalbavancin. However, since dalbavancin is a well known cyclic polypeptide as disclosed by Malabarba et al, a person having ordinary skill in the art at the time the

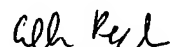
claimed invention was made would have been motivated to stabilize dalbavancin containing composition in accordance with the method disclosed by Sawai et al in order to provide stable dalbavancin-containing compositions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev


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GROUP 1200